

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Danette Vanessa Choi Confirmation : 9136  
Serial No. : 10/536,617 Examiner : Chawla, Jyoti  
Filed : March 13, 2006 Group Art Unit : 1794  
For : PAPAYA PUREE AND THE USE OF THE SAME

**DECLARATION PURSUANT TO 37 C.F.R. § 1.132**

**Filed Electronically**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Doctor Christa Wutschitz, MBA. hereby declare:

1. I am currently the head of II Department of Internal Medicine, Geriatric Centre Wienerwald, Jagdschlossgasse 59, 1130 Wien, Austria, since April 1, 2004.

2. During the medicine study and after my approbation I worked as an assistant at the medical university of Vienna. Afterwards I get a specialist for Internal Medicine (6 years), Gastroenterology and Hepatology (3years) in a general hospital in Vienna.

Between 2001 and 2004 I have been working as a Gastroenterologist in the III Department of Internal Medicine, Geriatric Centre Wienerwald.

Since 1997 I run an ordination for Internal Medicine, Gastroenterology and Hepatology in Vienna.

3. I have reviewed the above-identified U.S. patent application and the Office Action dated April 2, 2009 issued thereon. It has been explained to me that in the Office Action, all the claims have been rejected over a few cited references.

4. It is my understanding that the claims of the above-referenced patent application are directed to, among others, a papaya puree preparation, methods for making such

papaya puree preparation, as well as administering such a preparation to treat certain conditions or to improve the health of certain subjects.

5. I performed a clinical study to evaluate the efficacy of a papaya puree preparation as claimed in the above-noted U.S. patent application (Caricol®) with respect to the treatment of a gastroenterological condition, i.e., chronic obstipation, as compared with that of a customary papaya fruit pulp. The full description of the study and the results obtained are presented in the attached Exhibit A.

There is no relationship between me and the Applicant and I do not have any financial interest or benefit from the application.

7. Based on the results of the aforementioned clinical study, I am of the opinion that the papaya puree preparation according to the above-noted patent application has a surprising and significant efficacy in improving the bowel habit of the patients. This efficacy is not observed in the customary papaya fruit pulp.

8. To the best of my knowledge, no other papaya puree preparation has been known or reported as having such an efficacy for treating a gastroenterological condition as exhibited by the papaya puree preparation according to the above-noted patent application.

9. I hereby declare that all statements made herein and of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 and such willful statements made may jeopardize the validity of the application or any patent issued thereon.

  
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Christa Wutschitz, MD, MBA

  
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Date